

**Nucleic Acid Amplification Testing for Chlamydia and
Gonorrhea**

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
Bureau of Laboratories**

Request for Proposal (RFP)

Required Letter of Intent Due:

Friday, May 13, 2011

Full Proposal Due:

June 17, 2011

**Nucleic Acid Amplification Testing for Chlamydia and
Gonorrhea
MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**

Request for Proposal (RFP)

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Nucleic Acid Amplification Testing for Chlamydia and Gonorrhea

Request for Proposal

PART I: GENERAL GUIDELINES AND INFORMATION

A. INTRODUCTION/BACKGROUND

Chlamydia (CT) and gonorrhea (GC) are the most reported communicable diseases in Michigan. Historically, the Michigan Regional Laboratory System (RLS) has provided testing for these agents at up to six state, county, and city labs. Each laboratory provided testing on both a fee-for-service and a pre-paid voucher system. Annual testing volumes consist of 60,000 to 70,000 pre-paid tests and an additional 15,000 to 30,000 fee-for-service tests. Funds for the pre-paid voucher system were distributed through the Comprehensive Grant Agreement and consisted of state and federal funds provided through the Family Planning, STD, and Adolescent Health Programs at the Michigan Department of Community Health (MDCH). Each laboratory was responsible for billing functions associated with fee-for-service testing.

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A cost analysis of the nucleic acid amplification testing (NAAT) currently performed by the RLS showed potential cost saving of \$165,000 if all the testing was centralized to a single laboratory and savings of approximately \$100,000 if testing were conducted at only two laboratories. Most of the projected savings is associated with decreased quality control costs for larger test batches, decreased proficiency testing costs, decreased disposable costs, and increased automation.

Beginning in FY 2012, NAAT testing will be performed at two laboratories within the current RLS. Cost savings, along with turnaround time for testing and continuity of operations were the basis for this decision. Under this Request for Proposal, applicants are invited to apply for funding to perform 20,000 to 25,000 pre-paid tests and 5,000 to 10,000 fee-for-service tests. The exact test volumes will be determined based on the location of the laboratory selected and the availability of funding.

B. AVAILABLE FUNDS

MDCH intends to provide financial support activities by way of the Comprehensive Grant Agreement with the local public health agency selected. The laboratory selected will be paid based on their quality assurance plan and proposed cost per reportable result. The initial award will be based on estimated test volumes for agencies assigned to submit specimens to the contracted lab. Adjustments to the award will be made quarterly based on actual test volume. A total of one award is expected to be made in response to this RFP. MDCH reserves the right to not make an award as a result of this RFP process if it is deemed in the best interest of the Infertility Prevention Project and the Department.

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Funding awarded under this RFP will be planned for a 12 month (one year) period, based on availability of funding. Successful applicants will be issued a one year award for the period

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October 1, 2011 - September 30, 2012. ~~The award~~ will be extended annually for up to three additional years based on successful implementation of program objectives and continued availability of funds.

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C. APPLICANT ELIGIBILITY

It is the intent of MDCH to fund an existing Regional Laboratory with proven experience providing nucleic acid amplified testing (NAAT) for the STD, Family Planning, and Adolescent Health programs. Only Regional Laboratories currently providing GC and CT testing services are eligible to apply.

Eligible applicants include:

- Detroit Department of Health and Wellness
- Kalamazoo County Health and Community Services
- Kent County Health Department
- Saginaw County Health Department

D. SCOPE OF WORK

The successful bidder will provide CT/GC testing using a NAAT specified by MDCH. The bidder will purchase all reagents and obtain necessary equipment based on contract pricing available through the State of Michigan. The applicant must demonstrate an ability to perform high quality, cost-efficient testing within the specified timeframe as well as maintain appropriate records associated with quality control, equipment maintenance and quality assurance. The successful bidder will follow testing procedures provided by MDCH.

Applicants will perform fee-for-service testing for providers that submit specimens billed to Medicaid, Plan First, or to the submitter. The successful bidder will be responsible for packaging and shipping collections kits for all billed and non-billed tests for all submitters assigned to their laboratory.

D.1 PERFORMANCE STANDARDS

All applicants awarded funding by MDCH for CT/GC testing must:

1. Perform testing use the Gen Probe APTIMA Tigris system.
2. Maintain CLIA certification.
3. Subscribe to and successfully participate in proficiency testing for CT/GC.
4. Enter all specimens and report results in StarLIMS. Data entry should include all fields associated with race, ethnicity, date of collection, gender, specimen type, provider type, reason for test and all other fields required for regulatory compliance.

5. Initiate testing on the day the specimen is received by the laboratory and no later than one calendar day after the specimen is received.
6. Perform testing Monday – Friday, except for State Of Michigan holidays.
7. Participate in quarterly Michigan Infertility Prevention Program Alliance (MIPP) meetings held in Lansing.
8. Provide a quarterly report that include test volumes, turn around times, and a summary of any quality assurance issues encountered and action taken to resolve them. Average turn around times shall not exceed 4 days, including weekends.
9. Work with MDCH staff to resolve data integrity issues that are found when quarterly IPP reports are prepared for the Centers for Disease Control and Prevention (CDC).
10. Maintain an adequate inventory of reagents and disposables to insure no interruptions in testing.
11. Establish reimbursement agreements with relevant Medicaid Managed Care Provider Networks to secure third party reimbursement for billed tests submitted for eligible Medicaid patients.
12. The laboratory will test appropriately collected specimens from Medicaid Provider Networks even in the absence of a reimbursement agreement with that provider. The STD, Family Planning, or Adolescent Health Programs will reimburse the testing laboratory the comprehensive agreement, cost per reportable test for rejected charges as funding permits.
13. Follow a quality system plan equivalent to the Department’s plan including but not limited to quality control intervals, occurrence management, personnel assessment (education, training, and competency),

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PART II: APPLICATION PROCESS

A. NOTICE OF INTENT TO APPLY

It is **required** that applicants submit an *Intent to Apply* form (*Appendix A*) by 5:00 p.m. Eastern Standard Time (EST) on **Friday, May 13, 2011**. Submission of an “Intent to Apply” form is non-binding but will be used by MDCH to adequately prepare for the review of submitted proposals. Applicants who do not submit this form or miss the deadline set above, **ARE NOT** eligible to submit a complete application. Forms may be submitted via fax or email.

Submit to: James Rudrik, Ph.D.
Michigan Department of Community Health
Bureau of Laboratories
3350 N. ML King Jr Blvd

Lansing, MI 48906

(517) 335-9631 (fax) or rudrikj@michigan.gov

Receipt of *Intent to Apply* forms will be confirmed via email within two business days of receipt. If confirmation is not received in this time period, contact Dr. Rudrik at (517) 335-9641 immediately.

B. QUESTIONS REGARDING THE RFP

All questions about this RFP **MUST** be submitted in writing. **Questions will be accepted via fax (517) 335-9631, or email rudrikj@michigan.gov.** Final questions and requests for clarifications must be received by 3:00 pm, Friday, May 27, 2011. Questions will be responded to within three business days of receipt. Additionally, MDCH will collate all questions and answers and distribute them to applicants who have submitted a letter of intent via a Frequently Asked Questions (FAQ) Document. The frequently asked question document will be posted on MDCH's internet website; <http://www.michigan.gov/mdch> under request for proposals link. Questions that have not been submitted in writing will not be answered.

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C. SUBMISSION/ REVIEW REQUIREMENTS AND TIMELINE

1. Submission

Proposal packages must be RECEIVED by **3:00 p.m. Eastern Standard Time, on Tuesday, June 17, 2011.** **LATE APPLICATIONS WILL NOT BE ACCEPTED OR REVIEWED.** Faxed, or e-mailed proposals WILL NOT be accepted.

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Applicants are required to submit the signed original and four (4) copies of the proposal package. Submit proposals to:

James T. Rudrik, Ph.D.
Microbiology Section Manager
Michigan Department of Community Health Bureau of Laboratories
3350 N. ML King Jr Blvd
Lansing, MI 48906

Phone – if required for express hand delivery – (517) 335-9641

2. Rejection of Proposals

MDCH reserves the right to reject any and all proposals received as a result of this RFP. All timely proposals will undergo a technical review to determine compliance with the minimum requirements outlined in the Checklist for a Complete Proposal (Appendix E). Incomplete proposals may not be reviewed and notification will be provided.

3. Review of Proposals

Proposals submitted in response to this RFP will be reviewed and evaluated by a panel of individuals who have expertise/experience in relevant areas. All proposals will be scored by reviewers according to pre-established criteria. Scoring criteria will be responsive to the requirements of this RFP. The relative weight that each component of the proposal will receive in the review process is described in the narrative specifications.

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4. Notice of Award

Notices of Award are expected to be made by July 8, 2011.

5. Incurring Costs

All awards are contingent on the availability of funds and approval by the State Administrative Board. MDCH is not liable for any costs incurred by applicants prior to issuance of a contract signed by all required parties.

III. FORMAT REQUIREMENTS

A. CONTENT OF PROPOSAL PACKAGE

A complete proposal package will consist of:

1. Proposal Cover Sheet (*Appendix B*), signed by authorized agency representative(s)
2. Narrative Proposal
3. Budget Rationale

Applicants are encouraged to refer to the Proposal Checklist (*Appendix C*) in preparing their proposal package, and order the document according to this guideline.

B. FORMATTING/PACKAGING

1. Sequentially number all pages, including attachments and appendices
2. Include a table of contents for the entire package submitted
3. Do not staple or bind any of the copies submitted to MDCH. (Rubber bands or binder clips are acceptable)
4. Use 8 ½" by 11" paper
5. 12 point font; budgets, figures, charts, tables, figure legends, and footnotes may be smaller in size, but must be readily legible.
6. Use 1" margins (top and bottom, left and right)
7. Write on single side of page only
8. The narrative section is not to exceed 10 pages (Sections 1-6)
9. The structure and lay out of the proposal must follow the format outlined in this RFP.

Part V: PROPOSAL OUTLINE

The proposal should provide the following information using these headings and subheadings.

A. PROPOSAL COVER SHEET

Complete the Proposal Cover Sheet (*Appendix B*)

B. TABLE OF CONTENTS

Attachments must be paginated and listed in the Table of Contents.

C. PROPOSAL NARRATIVE (75 POINTS TOTAL)

The following outline must be adhered to for development of the proposal narrative.

1. Organizational Capacity (10 points)

Provide an organizational chart (**as Attachment A**) that clearly shows individuals responsible for management oversight (including laboratory manager and CLIA laboratory director), billing, data entry, and testing for this project. Include contact information (telephone and e-mail) for each individual. In the narrative, outline key staff, their credentials, experience relevant to this RFP, and reporting lines. Identify any new positions that will be necessary to complete the work outlined in this contract or vacant positions that will be filled. Describe your facility's staffing plan to expand testing from its current volume to approximately 30,000 annually. Include a description of the quality system and safety programs for the laboratory.

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2. Equipment (10 points)

MDCH will arrange to have a Gen Probe APTIMA Tigris instrument available for the successful applicant. This instrument performs automated specimen testing with a minimum of hands-on time required by laboratory. This instrument is quite large (68"W x 72"H x 36"D plus Gen Probe requires a minimum of 36" service space on all sides of the instrument), weighs approximately 1,500 pounds and requires a 220V outlet for operation. It is anticipated that the equipment could be ready for installation as soon as the ~~award~~ is ~~made~~. Please provide the following information:

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- Provide a floor plan (**as Attachment B**) showing your proposed location for the instrument. MDCH is not responsible for any construction or renovation costs associated with the installation of this instrument.
- Within the narrative, provide a proposed timeline for installation, training, and verification studies on the new instrument. Since exact information about instrument availability from Gen Probe is not available, the timeline can use a scale of weeks rather than specific dates.

- Provide a detailed plan on how your laboratory will continue to test specimens using the current DTS 800 system until the new instrument is ready for use.

3. Training (5 points)

- Gen Probe provides Tigris training for two individuals in San Diego, CA at no charge. The training and travel time require a one week commitment from each individual. Please identify the two individuals who will be sent for training, and express a commitment to their participation. Explain how testing will be performed while these individuals attend training.

4. Reagent Storage (5 points)

- In order to contain shipping costs, reagents and other disposables are usually ordered on a quarterly basis. Describe your facility's ability to provide storage for this volume of materials. This includes both refrigerated and room temperature storage. Please indicate storage locations of the floor plan required for item #2.

5. Past Performance (15 points)

- Provide a copy of proficiency testing results for the last two calendar years **(as Attachment C)**.
- The CPBC contract requires that laboratories perform testing every business day the facility is opened. Test results guide treatment decisions and program performance is judged based on the number of individuals treated within 14 and/or 30 days of specimen collection. To demonstrate your facilities testing turn around time, please provide turn around time reports for specimens received during the following time periods: April 5 – 9, 2010; July 5 – 9, 2010; November 8 – 12, 2010; and December 27 – 31, 2010. Turn around time is defined as the number of days from and including the date received to the date the result is validated (EPIC) or released by panel (StarLIMS). The report should include number of specimens tested. For simplicity, weekend days ARE included in the calculation.
- Discuss any changes your facility can/will make to enhance turn around time.

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6. Continuity of Operations (5 points)

- Describe your plan to continue to provide testing if a natural or intentional event makes your facility unusable for any time period greater than 24 hours.
- Describe you plan to continue testing if the Tigris requires repairs that take longer than 48 h.
- The successful applicant will be expected to back-up the Lansing laboratory in the event of instrument or facility failure. Describe what steps your facility would take to manage this increased volume if such an event occurs.

7. Budget Preparation (25 points) Attachment D

Payment for testing will be based on a cost per reportable result. Please submit a budget that provides a final cost per reportable result. Provide a detailed narrative that justifies and fully describes each item for the figure you provide. Items that may be taken into consideration include, but are not limited to: reagent costs (see Appendix D for current contract pricing), disposables (pipette tips), consumables (paper, paper towels, bleach), labor (data entry, testing, inventory), administrative time (result checking, turn around time reports, QA/QC review and reports, attending MIPP meetings), waste disposal, record storage, specimen tracking, overhead expenses. MDCH will not cover construction or remodeling expenses. The cost per test figure should cover the initial budget period from October 1, 2011 to September 30, 2012.

Nucleic Acid Amplification Testing for Chlamydia and Gonorrhea**INTENT TO APPLY FORM**

Applicant Agency

Address

City

State

Zip Code

Phone

Fax

Contact Person

Title

Email

Signature of Authorized Representative

Date

Please Print Name and Title

Please fax or email to:

James Rudrik, Ph.D.

(517) 335-9631 (fax)

rudrikj@michigan.gov

Nucleic Acid Amplification Testing for Chlamydia and Gonorrhea

PROPOSAL COVER SHEET

Legal name of organization applying: _____

Authorized Agent: _____ Phone: _____

Contact Person for this application: _____ Phone: _____

Address: _____ Fax: _____

City/State/Zip: _____

E-Mail Address: _____ Website: _____

1. Cost per reportable result: _____

Signature, Authorized Representative

Date

Typed Name and Title

Proposal Checklist

- ☐ Cover Sheet
- ☐ Proposal Checklist (this form with each item checked off as completed)
- ☐ Table of Contents
- ☐ Proposal Narrative
- ☐ Budget Narrative
- ☐ Required Attachments
 - ☐ A. Organizational Chart
 - ☐ B. Floor plan
 - ☐ C. Copy of proficiency testing results for calendar years 2009 & 2010
 - ☐ D. Proposed Budget 10/1/11-9/30/12

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Have you followed the required format?

- ☐ ALL pages are sequentially numbered, including attachments
 - ☐ Narrative (Sections 1-6) does not exceed 10 pages
 - ☐ 12 point font is used throughout (budgets, figures, charts, tables, legends and footnotes may be smaller in size, but must be readily legible)
 - ☐ 8½" x 11" paper is used
 - ☐ Margins are 1" on all sides
 - ☐ The proposal is written on one side of the page only
 - ☐ The proposal is not bound or stapled
- ☐ Have you prepared the **original and four copies** for submission?



**Attachment B
Price Proposal**

| Item No. | Gen Probe Catalog #ID | Description | Unit | Unit Cost |
|----------|-----------------------|---|------|------------|
| 1. | 301032 | APTIMA COMBO2 Assay (100 tests) | EA | \$846.28 |
| 2. | 301130B | APTIMA COMBO2 Assay (4 x 250 tests) | EA | \$8,462.80 |
| 3. | 301088 | APTIMA CT Assay (100 tests) | EA | \$689.33 |
| 4. | 301199 | APTIMA CT Assay (250 tests) | EA | \$1,722.50 |
| 5. | 301091 | APTIMA GC Assay (100 tests) | EA | \$689.33 |
| 6. | 301048 | APTIMA Auto Detect Reagent | EA | No Charge |
| 7. | 301040 | APTIMA Urine Specimen Collection Kit | EA | No Charge |
| 8. | 301041 | APTIMA Unisex Swab Specimen Collection Kit | EA | No Charge |
| 9. | 301162 | APTIMA Vaginal Swab Specimen Collection Kit | EA | No Charge |
| 10. | 302101 | Bleach Enhancer | EA | \$89.90 |
| 11. | 105049 | Tips, Rainin P1000 | EA | \$162.00 |
| 12. | 901121 | Tips, 1000 ul conductive, liquid sensing | EA | \$678.72 |
| 13. | 302224 | TIGRIS APTIMA CT (2 x 50 test) | EA | \$689.33 |
| 14. | 302225 | TIGRIS APTIMA GC (2 x 50 test) | EA | \$689.33 |

Additional Items for TIGRIS System provided As Needed at **NO CHARGE**:

| Item No. | Description |
|----------|---|
| 301191 | TIGRIS Aptima Run Kit |
| CL0040 | CAPS, TCR/SEL. (CL0038) DIAG |
| CL0041 | CAPS, AMP/P.R.S (CL0045) DIAG |
| 501616 | TIGRIS Spare Caps, 30mL tube (501213) DIAG |
| 501602 | TIGRIS Caps, PP mL, TCR-B APTIMA 2X50 |
| 501603 | TIGRIS Spare Caps HDPE, 10mL Recons Aptima 2X50 |
| 501604 | TIGRIS Spare Caps, PP, 60mL, TCR Aptima 2X50 |
| 302380 | TIGRIS Aptima System Fluid Preservatives |
| 302382 | TIGRIS Aptima Assay Fluids |
| 105668 | Penetrable Caps |

Notes:

DTS Sites are to receive at "NO CHARGE" (2) #301040, #301162 or #301041 kits for every (1) Aptima Reagent kit (Combo & CT & GC) ordered and (1) #301048 for every (3) Aptima Reagent kit (Combo & CT & GC) ordered.

The TIGRIS site is to at "NO CHARGE" receive (20) #301040, #301162 or #301041 kits for every (1) Aptima Reagent kit (#301130B) ordered, (2) for every TIGRIS CT & GC Kit ordered & (5) for every #301199 kit ordered.

Each site will pay \$62.50 each on #301040, #301162 & #301041 and \$45.00 on #301048 each when ordering outside the terms of the contract. The #301040, #301162 & #301041 kits will be a monthly allotment monitored and ordered for MDCH by the Gen-Probe Sales Rep. The #301048's will be ordered by each individual site at time of order placement.